

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant.

C.A. No. 23-152-CFC

VANDA PHARMACEUTICALS INC.,

Plaintiff,

v.

APOTEX INC. and APOTEX CORP.,

Defendant.

C.A. No. 23-153-CFC

**PLAINTIFF'S OPENING BRIEF IN SUPPORT OF
MOTION TO STRIKE AFFIRMATIVE DEFENSES AND TO
DISMISS COUNTERCLAIMS PREMISED ON THE
JANUARY 2021 SCHEDULING CONFERENCE**

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INTRODUCTION AND NATURE AND STAGE OF THE PROCEEDINGS

The threshold legal issue before the Court is whether a telephonic scheduling conference in a prior action permanently and irrevocably nullified Vanda's future patent rights. As defendants would have it, in mere seconds, Vanda surrendered its right to assert its patents (including those not in existence) against defendants. Vanda did all this, defendants posit, for the sole benefit of delaying a trial that Vanda repeatedly stated it was happy to litigate as scheduled.

Defendants' argument turns on a hyper-literal reading of two sentences of transcript. But the broader context confirms that the Court did not order—nor did Vanda agree to—the surrender of patent rights. Indeed, basic due process principles preclude that conclusion. To intelligently relinquish such rights, advance notice is required, as is Vanda's clear assent. None of that happened here.

Nor do any of the events that followed the conference remotely suggest that Vanda had abandoned its patent rights. Days after this call, Vanda twice informed defendants of its position that Vanda retained its right to assert patents in *other* cases. Fully aware of Vanda's position, defendants joined with Vanda in submitting the stipulated scheduling order, which moved the trial date. Defendants cannot plausibly claim that they lacked knowledge of Vanda's current position then. And the resulting order never suggested Vanda was forever barred from asserting new patents.

When Vanda later dismissed patents from the earlier action, the parties carefully negotiated covenants-not-to-sue. And when defendants sent renewed paragraph IV letters to Vanda in June and September 2022 to address the '129 patent (which issued *during* the March 2022 trial), *neither* defendant asserted that the January 2021 scheduling colloquy rendered the '129 patent unenforceable. None of this is consistent with defendants' position here.

Vanda commenced these actions on December 27, 2022, and defendants filed answers and counterclaims on February 27, 2022. Vanda moves to strike the affirmative defenses and to dismiss the counterclaims premised on this threshold issue.

SUMMARY OF ARGUMENT

I. During a telephonic scheduling conference, the parties agreed that Vanda would not assert additional patents following a specified cutoff date *for the trial scheduled for March 2022*. That is the only reasonable interpretation of the exchange, given its context and content. It is the only interpretation that is consistent with due process. And it is the only interpretation that accords with the parties' subsequent interactions. During this scheduling conference, Vanda's counsel did not, through a spontaneous oral exchange, somehow cause Vanda to forgo patent rights that did not even yet exist.

II. The colloquy in question, moreover, does not provide defendants a meritorious counterclaim or affirmative defense. There was no "agreement" by Vanda,

and surely not one enforceable by the “strong medicine” of judicial estoppel, as an equitable remedy to defendants’ reliance, or as an implied license or covenant not to sue. Nor has Vanda evinced, at any point, the bad faith necessary to justify the remaining extraordinary measures that defendants request.

STATEMENT OF FACTS

A. The prior litigation

This is a patent-infringement litigation between Vanda and defendants concerning defendants’ generic tasimelteon products. The first litigation (consolidated under C.A. 18-651-CFC) commenced in April 2018 when Vanda asserted five patents against Teva and then against Apotex and MSN. *Vanda I* was initially set for a July 2021 trial. During the litigation’s pendency, Vanda continued to make new discoveries, file and obtain new patents, and assert new infringement claims against defendants.

In August and October 2020, Vanda filed new complaints asserting patent infringement claims related to two then-recently-issued patents (’510 and ’511). C.A. 20-1104 (Teva), 20-1333 (Apotex). The Court invited the parties to advise whether to consolidate the new cases. *See* C.A. 20-1104 at D.I. 12. This prompted the parties to jointly submit a letter to the Court in which they proposed a July 2022 trial date for the ’510 and ’511 patents; Vanda additionally suggested that, “if the Court prefers, Vanda [was] amenable to integrating” the new cases with the already pending

litigation and “moving the July 19, 2021 trial date by approximately nine months,” to allow for consolidation of the new patents. Ex. 1 at 2. Defendants objected to any further extension of the trial date. *Id.*

B. The scheduling conference

On January 8, 2021, the Court held a telephonic scheduling conference. Ex. 2. Vanda reiterated its proposal to consolidate the case, and move the trial back nine months to July 2021. *Id.* at 5. That approach made sense, Vanda explained, because the generics certified they could not enter the market until at least December 2022. But Vanda was “perfectly happy either way”—to consolidate the cases and delay the trial or proceed along separate schedules and maintain the earlier trial scheduled for July 2021. *Id.* at 6-7. Defendants opposed delaying the July 2021 trial, expressing concern that delay would hinder resolving the litigation before December 2022. *Id.* at 12-13.

The December 2022 date loomed large throughout the conversation. The Court expressed a strong preference for holding only one trial and focused on the December 2022 date, which both made the trial less urgent as compared to other cases on the Court’s docket and meant defendants would not suffer harm from a delay that would not threaten the December 2022 date. As the Court remarked: “I have over 150 ANDA cases on my docket, so the idea that I’m going to do two

ANDA trials when I could do one and I wouldn't harm the parties ... [is] not something I really welcome or think is wise.” *Id.* at 11-12, 16.

Defendants then raised another concern with delaying the trial: that Vanda may later assert additional patent infringement claims and seek to move the trial. Ex. 2 at 16. The Court asked Vanda's then-counsel “when can you commit that we're not going to have any more patents added *to this case*?” *Id.* at 20 (emphasis added). Counsel responded that consolidating the cases would naturally impose a cutoff and that “I have not spoken with the clients about what that cutoff is. But we fully recognize we can't just keep adding patents all the time and have this be a moving target, and so we'd certainly be happy to talk to the clients” about what other patents were “in the pipeline” in order to set a cutoff date. *Id.* at 20-21.

The Court then asked defendants if they would be amendable to “put everything on hold, stop the case where it is, and then we restart it at some later date,” leaving time for a decision to issue before December 2022. Ex. 2 at 24. Defendants reiterated that their preference was to move forward with the first trial as scheduled, on the theory that the resolution of that trial would resolve the additional patents “without the added expense of litigating” them. *Id.* at 26 The Court called this suggestion a “non-starter;” assuming that Vanda would not “stipulate that they would be bound” by the outcome of the first trial and thereby waive its right to assert its patent rights in future litigation. *Id.* at 26-27. Vanda agreed. *Id.* at 27.

Vanda’s counsel suggested that the parties “confer and come up with a single trial date with a drop-dead date after which no new patents will come in.” Ex. 2 at 28. All eventually agreed. *Id.* The Court set a new trial for March 2022 and instructed the parties to “go back and work out” a “drop-dead date by which any patents can be added *to the case.*” *Id.* at 29 (emphasis added).

The Court then stated: “Mr. Groombridge, what you have to tell your client is that means they should not plan on ever getting to litigate in another case patents associated with these products.” *Id.* This remark was the first and only statement throughout the scheduling conference that could have implied any sort of limitation on Vanda’s ability to assert additional patents in future cases involving defendants’ tasimelteon products. Without any additional discussion or consideration of the issue or a pause to confer with his client, counsel tersely responded “Yes, we understand, Your Honor.” *Id.*

C. The resulting scheduling order

Following the conference, Vanda and defendants conferred on a schedule, ultimately submitting a joint proposed scheduling order (Ex. 3), which the Court entered without meaningful alteration (Ex. 4). The order stated that “Vanda shall assert any additional patents against Defendants *as part of this Hatch Waxman litigation* by March 15, 2021.” Ex. 4 ¶ 2 (emphasis added); *accord id.* ¶¶ 6, 8.

The order made no mention of disclaiming future patent claims. Vanda initially proposed a footnote clarifying that Vanda could assert causes of action arising after the cutoff date—it proposed language that “nothing in this Order shall be deemed to prevent Plaintiff from asserting any cause of action against Defendants after April 30, 2021 for infringement of additional patents arising from Defendants’ activities with respect to generic tasimelteon.” Ex. 7 at 9 n.1. Defendants objected and struck it from the draft based on the Court’s statement at the scheduling conference, but they did not propose such a limitation be made part of the order. *Id.* Although Vanda accepted defendants’ edit to achieve a stipulated schedule, it did so only after expressly reiterating that it disagreed that the scheduling conference in any way limited Vanda’s right to assert causes of action in future cases. Ex. 8.

D. The current action

On July 6, 2021, after the cutoff date, Vanda filed the application that became the ’129 patent, which issued on March 29, 2022, the second day of trial in *Vanda I*. In this litigation, Vanda has asserted the ’129 patent against defendants.

ARGUMENT

The scheduling conference colloquy does not bar Vanda from asserting the ’129 patent. Rule 12(b)(6) requires a court to dismiss a counterclaim that “fail[s] to state a claim upon which relief can be granted,” while Rule 12(f) allows “strick[ing] from a pleading any insufficient defense.” *Baxalta Inc. v. Bayer Healthcare LLC*,

2020 WL 5445375, at *2-3 (D. Del. 2020). The Court should do so for the counter-claims and defenses premised on the scheduling conference because applicable law precludes defendants from prevailing.¹

I. The scheduling-conference colloquy did not, and could not consistent with due process, foreclose Vanda’s patent rights.

The only reasonable interpretation of the January 2021 scheduling conference is that the Court would set a date by which Vanda would need to assert any new patents for inclusion in a March 2022 trial. Construing it vastly more broadly to limit Vanda from bringing any future patent litigation against defendants *ever*—including as to patents that did not yet exist—would defy due process.

A. Patent rights are property interests protected by the due process clause (*Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627, 642 (1999)), and each patent is a distinct property right (*Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 599 (Fed. Cir. 1985)). Because “procedural due process requires notice and an opportunity to be heard” (*Mancini v. Northampton Cnty.*, 836 F.3d 308, 315 (3d Cir. 2016)), a court may not deprive a patentee of its right to exclude others without adequate notice and a reasonable opportunity for the patentee to defend its interests in those patents. *Gniotek v. City of Philadelphia*, 808 F.2d 241, 244 (3d Cir.

¹ For motions based on the pleadings, the Court considers “the allegations,” “attached exhibits,” and “matters of public record” and may consider “documents described or identified in the complaint” and “indisputably authentic documents.” *Morgan v. Scott*, 83 F. Supp. 3d 616, 621 (D. Del. 2015).

1986).

“The purpose of notice under the due process clause is to apprise an affected individual of, and permit adequate preparation for, an impending hearing which may affect their legally protected interests.” *United States v. Raffoul*, 826 F.2d 218, 222 (3d Cir. 1987). And “due process requires that an individual receive ‘an opportunity to be heard at a meaningful time and in a meaningful manner.’” *Cunningham v. R.R. Ret. Bd.*, 392 F.3d 567, 576 (3d Cir. 2004); *Burns v. United States*, 501 U.S. 129, 136 (1991) (“‘Th[e] right to be heard has little reality or worth unless one is informed’ that a decision is contemplated.”).

Defendants’ essential contention—that a two-sentence exchange at the end of a telephonic scheduling conference caused Vanda to lose a significant chunk of its patent portfolio against three future competitors—falls apart when viewed through these basic due-process requirements.

Vanda was never provided notice that, in the course of a telephonic scheduling conference, its counsel could be called upon to give away a significant portion of its patent portfolio. Because Vanda had no notice that this issue could possibly be presented, the hearing itself afforded *Vanda* no opportunity to meaningfully state its position on that matter. Indeed, Vanda’s counsel confirmed that he was not even authorized to set a cutoff date for bringing patents into the litigation without consulting with Vanda to know what patents were “in the pipeline” (Ex. 2 at 21), let alone

authorized to unilaterally give away a broad swath of potential future patent claims.²

B. The scheduling conference did *not* flagrantly violate Vanda’s due process rights because, as the transcript demonstrates, the discussion addressed which patent claims Vanda could bring in *that* litigation, not *any* litigation *ever*. Whatever cursory appeal defendants’ soundbite may have, reviewed as a whole and in context, the upshot of the conference was clear: Vanda could not later inject any additional patents into the litigation set for trial in March 2022 after the to-be-determined cutoff date.

From the beginning of the scheduling conference, Vanda consistently evidenced its view that the question was whether to have one trial or two, and, sensing the Court’s preference to have one, it suggested that any patent claims “in the pipeline” be folded into the case to promote judicial efficiency, though Vanda was “perfectly happy” to proceed with separate trials on schedule. Ex. 2 at 6, 21. Vanda proposed a “drop-dead” date after which no new patents could “come in” to the lawsuit, but by no means did Vanda propose that patents that could not come in for a March 2022 trial—for instance, because they did not exist—were forever forgone. *Id.* at 28.

For their part, defendants’ preference was that Vanda’s later-asserted patent

² Moreover, parties cannot be compelled to waive core property rights as a condition for receiving a trial. *Cf. Spaziano v. Fla.*, 468 U.S. 447, 455 (1984) (agreeing with the “premise that a criminal defendant may not be required to waive a substantive right as a condition for receiving an otherwise constitutionally fair trial”).

claims not be consolidated with the prior action *at all*, but rather that the original trial proceed as scheduled with Vanda continuing to file separate lawsuits to assert other patents. *E.g.*, Ex. 2 at 11. In other words, defendants' express preference was for any of Vanda's additional patents to be litigated separately, *not* to preclude Vanda from litigating its future patent claims entirely.

The Court displayed sensitivity to Vanda's interest in preserving its future legal claims, calling defendants' suggestion that the first trial would somehow resolve the issues for Vanda's other patents a "non-starter," which Vanda confirmed. Ex. 2 at 26-27. While the Court's statement at the very end of the telephonic conference that Vanda should not "ever" plan to assert future patent claims in "another case" (Ex. 2 at 29) could hyperliterally support a much broader implication, such an interpretation is squarely at odds with the overall tenor of the conference.

The prominence in the discussion of the December 2022 generic launch date also supplies essential context. Defendants expressed a concern that delaying the trial to July 2021 could delay their ability to enter the market in December 2022 if they ultimately prevailed. Ex. 2 at 12. To accommodate that interest, the Court selected a trial date in March 2022 to yield a decision in time. *Id.* at 29. And the parties agreed that Vanda needed to add any additional patents to "*this*" litigation by the selected date, and they would not postpone the trial. *Id.* at 20, 28. Defendants' point was never to say that Vanda must swear off all other patent claims forever. Rather,

the point was that the trial would not be moved again to accommodate unasserted patents after the cutoff date.

Nor is it fair for defendants to seize on statements made during a telephonic conference, attempting to elevate them to binding edicts. *Cf. Eddings v. Oklahoma*, 455 U.S. 104, 124 (1982) (Burger, C.J., dissenting) (remarking that “[e]xtemporaneous courtroom statements are not often models of clarity,” as a court cannot “be expected to frame each utterance with the specificity and precision that might be expected of a written opinion”).

Following that conference, the Court directed “Counsel to confer and submit a revised proposed scheduling order to the Court on or before January 15, 2021.” *See* C.A. 20-1104 (1/8/2021 minute entry). The parties reached a stipulated order providing a date by which “Vanda shall assert any additional patents against Defendants *as part of this Hatch Waxman litigation* by March 15, 2021.” Ex. 4 ¶ 2 (emphasis added). The Court never reduced to writing anything remotely suggesting that Vanda would be forever foreclosed from later asserting patents.

When Vanda dismissed the ’465 patent, it entered into a covenant not to sue stating expressly that Vanda “irrevocably and unconditionally covenants not to assert the ’465 Patent, or any patent claiming priority to the ’465 Patent, or any patent claiming priority to any patent or application to which the ’465 Patent claims priority” against defendants. Ex. 5. Thus, when they sought to foreclose future lawsuits,

the parties spoke clearly with express language. Moreover, by forming the covenant-not-to-sue, the parties displayed their mutual understanding that a future patent infringement action *was* otherwise still available.

After the '129 patent issued and was Orange Book listed, defendants sent Paragraph IV letters to Vanda in June and September 2022. Teva Case D.I. 8 at 7; Apotex Case D.I. 6 at A25-26. Neither Teva nor Apotex asserted that the '129 patent (or any other) was unenforceable based on the January 2021 scheduling conference.

Finally, construing the Court's comment as defendants propose would seem to foreclose Vanda from pursuing claims against defendants based on *any* patent *ever* issued related to tasimelteon. That cannot be. Hetlioz® was FDA-approved to treat nighttime sleep disturbances in Smith-Magenis Syndrome (SMS) in December 2020 (before the conference), and Vanda holds several patents relating to SMS that defendants carved out from their generic labels. Ex. 6. Defendants' position—which would seem to suggest Vanda could not assert its SMS patents against defendants if they market their products for the SMS-related indication—is implausible.

Vanda did not agree to permanently forgo its patent rights and the Court never ordered such an extraordinary result. Because defendants are wrong about what occurred, their corresponding counterclaims should be dismissed and defenses struck.

II. Defendants' legal theories each fail.

Apart from this fundamental defect, each of defendants' legal theories fail for

additional reasons.

A. Vanda is not equitably estopped.

Because Vanda never misled defendants, Vanda is not equitably estopped from asserting the '129 patent.

“Three elements are required for equitable estoppel to bar a patentee’s suit: (1) the patentee, through misleading conduct (or silence), leads the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer; (2) the alleged infringer relies on that conduct; and (3) the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim.” *Radio Sys. Corp. v. Lalor*, 709 F.3d 1124, 1130 (Fed. Cir. 2013).

First, Vanda did not do anything that could have possibly led defendants “to reasonably infer that [Vanda] did not intend to enforce its patent against the alleged infringer.” *Radio Sys.*, 709 F.3d at 1130. For reasons described above, at no point did Vanda relinquish patent rights. For this reason alone, defendants cannot have “been led to reasonably believe from [Vanda’s] conduct” that all future patent claims whatsoever were “abandoned.” *A.C. Aukerman Co. v. R.L. Chaides Const. Co.*, 960 F.2d 1020, 1042 (Fed. Cir. 1992).

Second, there is no possible way that defendants reasonably relied, let alone “detrimentally reli[ed]” on statements at the scheduling conference. *Radio Sys.*, 709 F.3d at 1130. On January 19, 2021—11 days following the conference—Vanda

shared a draft stipulation that clarified Vanda's view that it retained the right to assert future claims. Ex. 7 at 9 n.1. And three days after that, Vanda's counsel further confirmed this position. Ex. 8. Since Vanda twice informed defendants of its view of the meaning of the scheduling conference—11 days and 14 days following the conference itself—defendants cannot plausibly claim that they have been reasonably misled all the while.

Third, Defendants have not shown prejudice apart from their need to defend against a validly-asserted claim.

B. Vanda is not judicially estopped.

Judicial estoppel requires three elements: (1) the party “must have taken two positions that are irreconcilably inconsistent”; (2) “the party [must have] changed his or her position ‘in bad faith—i.e., with intent to play fast and loose with the court’”; and (3) judicial estoppel must be “‘tailored to address the harm identified.’” *Montrose Med. Grp. Participating Sav. Plan v. Bulger*, 243 F.3d 773, 779-80 (3d Cir. 2001).

First, taken as a whole, the record shows that Vanda's position regarding its patent infringement claims has never changed. Vanda's counsel did not take the position that Vanda would never again assert patents against defendants. And, as just recounted, in the days that followed the scheduling conference, Vanda twice asserted its position that it retained its rights to assert future patents.

Second, at most, Vanda’s position is the correction of an honest mistake—not bad faith. “[J]udicial estoppel does not apply ‘when the prior position was taken because of a good faith mistake rather than as part of a scheme to mislead the court.’” *Ryan Operations G.P. v. Santiam-Midwest Lumber Co.*, 81 F.3d 355, 362 (3d Cir. 1996) (citation omitted). “[C]areless or inadvertent” acts are not “equivalent to deliberate manipulation” that warrant “the ‘strong medicine’ of judicial estoppel.” *Id.* at 364.

Rather than impute to Vanda an intent to give away its valuable intellectual property rights—the lifeblood of the company—in exchange for moving a trial it was “perfectly happy” to litigate as scheduled (Ex. 2 at 6), the much more plausible explanation is that Vanda agreed to establish a date by which it had to assert any claims in order for them to be litigated in *that* trial, not *any* trial.

If there was a change in position—and Vanda submits there was none—it was at most a correction of a prior mistake. Vanda’s attorney simply did not appreciate the potentially sweeping import that defendants would later try to assign to the Court’s question in the moment. Indeed, Vanda’s good faith during the exchange is evident. Vanda suggested consolidating the actions to promote judicial efficiency and ultimately suggested the cutoff day to reconcile the Court’s desire for one trial and defendants’ concern about future delay. And, in the days that followed, Vanda made its position crystal clear to defendants.

Third, the dramatic sanction of judicial estoppel is not appropriately “tailored” to resolve this matter. *Montrose*, 243 F.3d at 784. Vanda’s position has been consistent from the start, and any seemingly contrary position was inadvertent. As such, judicial estoppel clearly is not “tailored” to this situation. *See id.* at 785 (“judicial estoppel is not so tailored unless, ‘at a minimum,’ the party to be estopped took inconsistent positions in bad faith”). Indeed, the inappropriateness of judicial estoppel is reinforced by the serious due process concerns that attend defendants’ interpretation of the scheduling conference. *See supra* at 8-10.

C. Vanda did not impliedly license Teva.

Vanda never agreed to license its entire future patent portfolio to Teva. Courts inquiring into whether a patentee has conferred an implied license must look for “an affirmative grant of consent or permission to make, use, or sell: i.e., a license.” *Wang Lab’ys, Inc. v. Mitsubishi Elecs. Am., Inc.*, 103 F.3d 1571, 1581 (Fed. Cir. 1997). An implied license “may arise by equitable estoppel, acquiescence, conduct, or legal estoppel.” *Winbond Elecs. Corp. v. ITC*, 262 F.3d 1363, 1374 (Fed. Cir. 2001).

Implied license by equitable estoppel: Vanda did not give “an affirmative grant of consent or permission to make, use, or sell to the alleged infringer”—Vanda never “communicate[d] that [Teva] will not be disturbed by the plaintiff patentee in the activities in which the former is currently engaged.” *Winbond*, 262 F.3d at 1374. On the contrary, Vanda has steadfastly protected its rights against Teva’s generic

product.

Acquiescence is plainly inapposite, as that doctrine is implicated only “where a plaintiff was bound to know that the royalties it received were for devices corresponding to the patent in suit, thus justifying defendant in concluding that plaintiff consented” to conduct it later characterizes as infringement. *Sun Microsystems, Inc. v. Versata Enters., Inc.*, 630 F. Supp. 2d 395, 411 (D. Del. 2009) (cleaned up).

Implied license by conduct is formed when “(1) a relationship exist[s] between plaintiff and defendant; (2) within that relationship, plaintiff grant[s] defendant a right to use plaintiff’s patents; (3) plaintiff receive[s] valuable consideration for the grant of right; [and] (4) plaintiff’s statements and conduct create[] the impression that plaintiff consented to defendant’s use of plaintiff’s patents.” *Tenneco Auto. Operating Co. v. Visteon Corp.*, 375 F. Supp. 2d 375, 384 (D. Del. 2005).

There is no relationship between Vanda and Teva. Rather, the “implied license defense is typically presented ‘when a patentee or its licensee sells an article and the question is whether the sale carries with it a license to engage in conduct that would infringe the patent owner’s rights.’” *Zenith Elecs. Corp. v. PDI Commc’n Sys.*, 522 F.3d 1348, 1360 (Fed. Cir. 2008); *Tenneco*, 375 F. Supp. at 384 (plaintiff supplied defendant the equipment giving rise to infringement claim).

Moreover, Vanda did not receive any “valuable consideration” from Teva. The only benefit even arguably conferred upon Vanda was the Court’s delay of the

trial. But during the scheduling conference, Vanda repeatedly said that it was “perfectly happy” to have it as scheduled. It strains all credulity to suggest that Vanda would bargain away numerous future patent claims to secure an extension of just a few months that it was happy to forgo. And, when the parties entered the stipulated scheduling order, defendants *knew* about Vanda’s position.

Lastly, Vanda’s “statements and conduct” in no way “created the impression that plaintiff consented to defendant’s use of plaintiff’s patents.” *Tenneco*, 375 F. Supp. 2d at 384. Rather, the Court itself identified only one benefit defendants were getting—a slightly earlier trial than Vanda’s proposal—*not* a forever license to Vanda’s entire Hetlioz®-related portfolio. Ex. 2 at 29.

Legal estoppel: For legal estoppel, the plaintiff must have “licensed or assigned a right, received consideration, and then sought to derogate from the right granted.” *Wang Lab ’ys*, 103 F.3d at 1581. Vanda’s statements during the scheduling conference are not a binding license of its patent rights. And there was no meeting of the minds at the scheduling conference that could form a patent license.

Moreover, under the Delaware statute of frauds, an oral agreement that cannot be performed within one year is not enforceable. *White Winston Select Asset Funds, LLC v. Good Times Restaurants, Inc.*, 2020 WL 5362636 at *1-2 (D. Del. Sept. 8, 2020); 6 Del. C. § 2714. An open-ended patent license or covenant-not-to-sue in perpetuity cannot, by definition, be performed within one year and thus falls within

the statute of frauds. *Solaia Tech. LLC v. ArvinMeritor, Inc.*, 2006 WL 695699 at *12-13 (N.D. Ill. Mar. 16, 2006). Further, Vanda did not receive any legally valid consideration from Teva for the supposed license.

D. The remaining Teva defenses and counterclaims lack merit.

Teva's additional assorted theories do not move the needle.

Unclean Hands: The defense of unclean hands requires a defendant to show that the plaintiff “conducted itself so as to shock the moral sensibilities of the judge ... or stated otherwise that [its] conduct was offensive to the dictates of natural justice.” *Honeywell Int’l, Inc. v. Universal Avionics Sys. Corp.*, 343 F. Supp. 2d 272, 321 (D. Del. 2004) (cleaned up). To satisfy the demanding standard, the plaintiff’s conduct must have been so egregious that it threatens the court’s “integrity” and make it the “abettor of iniquity.” *Ne. Women’s Ctr., Inc. v. McMonagle*, 868 F.2d 1342, 1354 (3d Cir. 1989). In *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245-246 (1933), the unclean hands finding was compelled by the plaintiff’s outright fraud, including bribing a witness. Vanda’s conduct is nothing of the sort.

Patent Misuse: To establish patent misuse, the alleged infringer must “show that the patentee has impermissibly broadened the physical or temporal scope of the patent grant with anticompetitive effect.” *Masimo Corp. v. Philips Elec. N. Am. Corp.*, 2015 WL 2406155, at *3 (D. Del. 2015). Because “[p]atent misuse turns on

whether the patentee has leveraged its patent beyond the rights granted” (*id.* at *5), “[i]t is not patent misuse to bring suit to enforce patent rights not fraudulently obtained” (*C.R. Bard, Inc. v. M3 Sys., Inc.*, 157 F.3d 1340, 1373 (Fed. Cir. 1998)). Vanda has not attempted to expand the scope of its patent rights.

“Oath Trifling”: Vanda is unaware of “oath trifling” ever forming a defense to patent infringement. In any event, the scheduling-conference statements were not under oath. 18B *Federal Practice & Procedure* § 4477.4 (3d ed. Apr. 2022 update) (describing the concept as “a person has asserted one position under oath, as either witness or party, and then seeks to advance an inconsistent position as a party”).

CONCLUSION

The Court should strike Apotex’s affirmative defense of estoppel and should strike Teva’s affirmative defenses of equitable estoppel, judicial estoppel, implied license, patent misuse, unclean hands, and “oath trifling” and dismiss Apotex’s and Teva’s counterclaims on these issues.

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